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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/738,446 | 12/16/2003 | Thomas D. Kelly | DI-5928 (112713-457) | 8102 |

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| EXAMINER | |
|---|---|
| DEAK, LESLIE R | |
| ART UNIT | PAPER NUMBER |
| 3761 | |
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| 05/03/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

SP

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/738,446 | KELLY ET AL. | |
| | Examiner | Art Unit | |
| | Leslie R. Deak | 3761 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-107* is/are pending in the application.

4a) Of the above claim(s) *1-13 and 39-107* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Amendment*

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

2. Accordingly, the After Final Amendment, filed 28 November 2006 is hereby entered. However, the amended claims do not overcome Examiner's restriction requirement based on original presentation, as explained below.

### *Election/Restrictions*

3. Newly entered and amended claims 99-107 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Inventions in claims 14-38 and newly entered claims 99-107 are directed to related inventions. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have materially different designs, since the newly presented claims comprise a balance chamber that is used in the regulation of fluid distribution in the medical fluid system claimed by applicant. Such a balance chamber creates a materially different mode of operation of the claimed device, rendering the inventions separately patentable. Furthermore, the

inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 99-107 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 14, 16-18, 33-35, 37, and 38 are rejected under 35 U.S.C. 102(b) as being anticipted by WO 99/29355 to Sternby.

In the specification and figures, Sternby discloses the device as claimed by applicant. With regard to claims 14, 33-35, Sternby discloses a dialysis apparatus that may perform hemodiafiltration comprising a medical fluid circuit 5, 12, with medical fluid supply (not shown, but the system comprises water supply and concentrate supplies via inlets 5, 6, 7), first pump10 to supply medical fluid to a filtration device 1, and a second pump 11 that pulls fluid from the filtration device (see FIGS 1, 4, page 5, lines 20-37). The circuit further comprises valves or clamps 14, 15 that may be operated to isolate

the filtration device from the remainder of the fluid circuit (see FIGS 1, 4). The device further comprises a controller 17 that controls the valves and the pumps, wherein the computer may be programmed (that is, *operable to*) to provide an infusion solution to the blood side of the filtration device in a postdilution operation (see FIG 4, page 7, lines 3-7).

With regard to claims 16-18, Applicant's recitation with regard to the operation of the controller is not a positive structural limitation and only sets forth what the controller is capable of doing. Apparatus claims cover what a device is, not what it does. See MPEP 2114. In the instant case, it is the position of the examiner that the Sternby device is capable of being programmed by an operator to control the pumps and valves as claimed by applicant, thereby meeting the limitations of the claim.

With regard to claim 37, Sternby illustrates that the medical fluid flow path comprises a drain line 12 to remove ultrafiltrate upstream of the location 21 in which medical fluid is delivered to the extracorporeal blood circuit (see FIG 4).

With regard to claim 38, Sternby discloses that the device comprises a conductivity sensor in the urea monitor 18, 19, 22, 23. The urea monitor is connected to the computer 17, which controls the operations of the valves and pumps (see pages 5-7). It is the position of the examiner that the computer is capable of (and thereby *operable to*) being programmed to control the pumps based on biosensor or conductivity measurements as claimed by applicant, thereby meeting the limitations of the claims.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/29355 to Sternby.

In the specification and figures, Sternby discloses the device substantially as claimed by applicant (see rejection above).

With regard to claim 36, Sternby fails to disclose that the device may be configured to alternately deliver fluid to the extracorporeal circuit either upstreamof downstream of the blood filtering device in a single embodiment. However, illustrates that the device may be configured for upstream delivery in the embodiment shown in FIG 3, and downstream delivery in the embodiment shown in FIG 4. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the embodiments illustrated by Sternby into a single structure capable of delivering fluid upstream or downstream of the filtration device in order to effectively balance patient needs, depending on whether patient parameters demand predilution or postdilution infusion.

8. Claims 15 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/29355 to Sternby in view of US 5,932,103 to Kenley et al.

In the specification and figures, Sternby discloses the device substantially as claimed by applicant (see rejection above).

With regard to claim 15, Sternby fails to disclose that the control scheme is configured to deliver a postdilution bolus in order to prevent patient hypotension. Kenley discloses a dialysis system and controller that uses fluid within the medical fluid system to administer a bolus to the patient in the event of patient hypotension (see column 8, lines 50-62). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to program the controller or computer disclosed by Sternby to deliver a bolus of postdilution fluid to prevent patient hypotension, as taught by Kenley.

With regard to claims 19-20, Sternby discloses that the device comprises a conductivity sensor in the urea monitor 18, 19, 22, 23. The urea monitor is connected to the computer 17, which controls the operations of the valves and pumps (see pages 5-7). It is the position of the examiner that the computer is capable of (and thereby *operable to*) being programmed to control the pumps based on biosensor or conductivity measurements as claimed by applicant, thereby meeting the limitations of the claims.

9. Claim is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/29355 to Sternby in view of US 5,591,344 to Kenley et al.

In the specification and figures, Sternby discloses the device substantially as claimed by applicant (see rejection above).

With regard to claims 21-26, Sternby fails to disclose that the bolus delivered to the patient comprises a rinseback volume delivered at the end of therapy. Kenley discloses a dialysis system configured to allow postdilution (see column 51, lines 14-20) that also uses dialysis fluid as a rinseback fluid that is communicated to the patient after the completion of therapy upon patient input as controlled by the valves, pumps, and optical sensors (see column 48, lines 1-35). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to program the system disclosed by Sternby to deliver a rinseback fluid to the patient after therapy, as disclosed by Kenley, in order to ensure all extracorporeal blood is returned to the patient.

With regard to claim 23 drawn to the automatic nature of the rinseback operation, it has been held that broadly providing an automatic means to replace a manual activity which accomplishes the same result is not sufficient to distinguish over the prior art. See MPEP 2144.04(III).

With regard to Applicant's recitations drawn to the operation of the controller, such limitations are considered by the examiner to lack positive structural limitations, and only setting forth what the controller is capable of doing. Apparatus claims cover what a device is, not what it does. See MPEP 2114. In the instant case, it is the position of the examiner that the devices disclosed by the prior art are capable of being programmed by an operator to control the pumps and valves as claimed by applicant, thereby meeting the limitations of the claim.

With regard to claims 27-32, Sternby fails to disclose that the bolus delivered to the patient comprises a prime volume delivered at the beginning of therapy. Kenley discloses a dialysis system configured to allow postdilution (see column 51, lines 14-20) that also uses dialysis fluid as a priming fluid that is communicated through the circuit before therapy as controlled by the valves, pumps, and air detectors of the circuit (see column 47, line 50 to column 46, line 27). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to program the system disclosed by Sternby to deliver a priming fluid to the circuit before therapy, as disclosed by Kenley, in order to ensure the extracorporeal circuit is ready for therapy.

With regard to claim 29 drawn to the automatic nature of the priming operation, it has been held that broadly providing an automatic means to replace a manual activity which accomplishes the same result is not sufficient to distinguish over the prior art. See MPEP 2144.04(III).

With regard to Applicant's recitations drawn to the operation of the controller, such limitations are considered by the examiner to lack positive structural limitations, and only setting forth what the controller is capable of doing. Apparatus claims cover what a device is, not what it does. See MPEP 2114. In the instant case, it is the position of the examiner that the devices disclosed by the prior art are capable of being programmed by an operator to control the pumps and valves as claimed by applicant, thereby meeting the limitations of the claim.

***Response to Arguments***

10. Applicant's arguments, see the preappeal conference request, filed 28 December 2006, with respect to the rejection(s) of claim(s) 14/38 under 35 USC 102 and 103 in view of US 5,470,483 to Bene have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Sternby and Kenley, as presented above.

***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

a. US 6,042,784 Wamsiedler et al

i. Hemodialysis apparatus with postdilution line

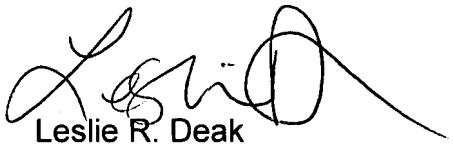
b. US 6,916,424 Collins et al

ii. Hemodiafiltration and fluid delivery

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie R. Deak
Patent Examiner
Art Unit 3761
19 April 2007